UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: Bair Hugger Forced Air Warming Devices Products Liability Litigation	MDL No. 15-2666 (JNE/DTS)
This Document Relates To: ALL ACTIONS	**DEFENDANTS' RESPONSE TO PLAINTIFFS' THREE BELATEDLY DISCLOSED ARTICLES**

At the hearing on June 12, Plaintiffs asked the Court to consider three articles they had not previously cited in their briefing on the Motion for Reconsideration or otherwise. The Court should not receive the articles because they are not relied upon by Plaintiffs' experts and are not admissible evidence that may be considered on a summary judgment motion. Even if the Court does consider the articles, they do not help Plaintiffs because they are irrelevant to the causation questions before the Court.

Defendants' Motion for Reconsideration is both a challenge to Plaintiffs' experts under Fed. R. Evid. 702 and a request for summary judgment under Rule 56. Under Fed. R. Evid. 702, Plaintiffs must demonstrate they have reliable expert testimony that meets their burden to prove causation by a preponderance of the evidence. *See Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006) ("The burden is on the party offering the expert testimony to prove that it is reliable."); *Bland v. Verizon Wireless, (VAW) L.L.C.*, 538 F.3d 893, 897 (8th Cir. 2008) (affirming exclusion of expert over argument that district court "abused [its] discretion by imposing a burden of proof tantamount to scientific certainty rather than the preponderance of evidence standard required by law."). In responding to a summary judgment motion, Plaintiffs must demonstrate that their evidence would be

admissible at trial. *See* Fed. R. Civ. P. 56(c); *O'Brien & Wolf, LLP v. Assoc. Banc-Corp.*, No. 11-CV-1253 (SER), 2013 WL 1104641 (D. Minn. Mar. 18, 2013) (noting that "only evidence that would be admissible at trial can be considered in a summary judgment motion"); *Tuttle v. Lorillard Tobacco Co.*, 377 F.3d 917 (8th Cir. 2004) (plaintiff "cannot rely on hearsay to avoid summary judgment"); *Mays v. Rhodes*, 255 F.3d 644, 648 (8th Cir. 2001) ("While we review the record in the light most favorable to . . . the non-moving party, we do not stretch this favorable presumption so far as to consider as evidence statements found only in inadmissible hearsay.").

None of Plaintiffs' experts cited any of the three articles in their reports or testimony, or in any supplemental affidavit. Plaintiffs offer only attorney advocacy to support the articles' conclusions, methods, and reliability. Fed. R. Evid. 703 (proponent must demonstrate that expert in the field would reasonably rely on the facts or data); Fed. R. Evid. 803(18) (to satisfy the exception to the rule against hearsay, statement in publication must be relied on by expert and the publication must be established as reliable). Accordingly, Plaintiffs have not satisfied their burden to establish admissibility of the articles under Fed. R. Evid. 702, 703, or 802, and the articles cannot be used to oppose summary judgment. *See Junk v. Terminix Intern. Co.*, 628 F.3d 439 (8th Cir. 2010) (affirming district court's grant of summary judgment after it concluded that EPA report relied on by plaintiff was inadmissible under Fed. R. Evid. 703 and 803(18)). Contrast that with Defendants' use of the Jeans study, the admissibility of which is supported by the verified Report of Dr. Jonathan Borak. Hulse Decl. DX11, Borak Rpt. ¶ 21. Even if the Court does consider the three inadmissible articles, they are irrelevant. None helps

Plaintiffs satisfy their burden of demonstrating their experts' opinions are reliable and that Plaintiffs can satisfy their burden of proof on general causation.

Lange

Lange's short 2019 abstract (Court Exhibit No. 1) does not address Plaintiffs' lack of evidence that the Bair Hugger system emits bacteria. Lange, who identifies himself as a lawyer, reports that some unidentified person cultured surface and air samples from "in and around 35 unique FAW devices actively in-use in operating room (OR) setting." Lange does not say whether those devices were Bair Hugger systems, as opposed to other forced air systems (*e.g.*, Stryker Mistral, Medtronic/Covidien WarmTouch, Cincinnati Sub-Zero WarmAir, Smiths Medical Level 1, or Medical Solutions "COCOON" Patient Warming System). The researcher's sampling "methods" are not well described, but it is clear from the information provided that sampling was not done "at the business end of the Bair Hugger—the perforated blanket." *Gareis*, 16-4187, ECF No. 306, Order at 3.

This study therefore does not support any argument that the Bair Hugger system emits colony-forming units that then reach the surgical site. It does nothing to undermine the Court's order in *Gareis* excluding Plaintiffs' alternative theory of causation. *See id.* (excluding Plaintiffs' expert testimony and evidence based on other sampling of the Bair Hugger hose because Plaintiffs failed to meet their burden under Fed. R. Evid. 104(b) "to support a finding that the fact does exist").[1]

[1] This article also provides no support for Plaintiffs' argument that the Bair Hugger causes infections by disrupting the supposed "force field" around the patient.

Sugai

Sugai (2018) (Court Exhibit No. 2) is irrelevant because it compares the warming effectiveness of the Covidien WarmTouch system and the HotDog system. It does not study the Bair Hugger system. Nor does Sugai report infection rates in either group. The report thus adds nothing to Plaintiffs' experts' opinions on whether the *Bair Hugger system* causes deep joint infections.

The Court also should disregard the article because it contains obvious false statements, which are strong evidence of its overall unreliability. The authors assert that the CDC has "issued a warning" that "[n]othing that blows air should be in an operating theater, if possible." The CDC has not issued any such warning. *Gareis*, 16-4187, ECF No. 156, Def. Mem ISO MIL No. 5, at 8 (explaining that the statement was made by an attendee at a meeting of the Advisory Committee to the CDC, and has never been the CDC's official position). These sentences echo similar false assertions first made by Dr. Augustine and later repeated by Plaintiffs in this litigation. At most, the authors' statements about the CDC are "dicta" lacking any support from the research they actually conducted. *Rosa v. City of Seaside*, 675 F. Supp. 2d 1006, 1013 (N.D. Cal. 2009) (finding that plaintiff's key scientific evidence, which consisted of statements in a report by a federal government advisory panel, were "the scientific equivalent of dicta" and therefore plaintiffs could not satisfy their burden of proof on products liability claims).

In addition, the *Journal of Anesthesia & Surgery*, an online journal published by OMMEGA publishers, is not listed on PubMed. Plaintiffs have not demonstrated that it is a reputable and reliable publication. Fed. R. Evid. 703, 803(18)(B). The Sugai article thus

is irrelevant, unreliable, and adds nothing to Plaintiffs' experts' opinions, even assuming Plaintiffs' experts considered the report—which they did not.

Sousa

Finally, Plaintiffs incorrectly suggest that Sousa (2016) (Court Exhibit No. 3) demonstrates that MSSA screening is ineffective, and claim that it contradicts the findings of the Jeans study. As the Sousa authors note, however, their study was "clearly underpowered" and too small to test whether MSSA screening significantly reduced infection rates. *Id.* at 236 ("Knowing this study would not be able to reach the figures necessary to be adequately powered, the authors were hoping to determine trends between groups"). Thus, according to the authors' express statements, it cannot support Plaintiffs' proposition. Fed. R. Evid. 104(b); *Gareis*, 16-4187, ECF No. 306, Order at 3. If there is *any* relevance to Sousa, it is that it actually *supports* the reliability of the Jeans study. Sousa observes that an adequately sized trial would require more than 10,000 patients to be screened. (Court Exhibit No. 3 at 238.) The Jeans study *did* include more than 10,000 patients (12,910 patients, to be exact). ECF No. 1720-1, DX10, Jeans, at 406.

Moreover, as Dr. Borak's report explains, the Jeans study was conducted on a patient population that included the same patient population as the McGovern study, and determined that MSSA screening was associated with lower infection rates in that population. Jeans strongly supports the contention of Defendants' experts that MSSA screening confounded the McGovern study. ECF No. 1720-1, DX11, Borak Rpt. ¶ 21b ("This study confirms that adoption of MSSA screening almost exclusively for patients using the non-[Bair Hugger] warmer confounded the results of the McGovern study.").

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Respectfully submitted,

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